CHAPTER 4
BIRTH DEFECTS INSTITUTE
[Prior to 7/29/87, Health Department[470]]

641—4.1(136A) Newborn screening policy. It shall be the policy of the state of Iowa that all newborns shall be tested for hypothyroidism, phenylketonuria (PKU), galactosemia, hemoglobinopathies, and congenital adrenal hyperplasia (CAH).

641—4.2(136A) Physician responsibility. The attending physician having hospital delivery privileges shall have the responsibility for ensuring that infants under the physician's care are screened. Parents or guardians shall be informed of the type of specimen, how it is obtained, the nature of the diseases being screened, and the consequences of treatment and nontreatment. Should a parent or guardian refuse the test, said refusal shall be documented in writing and will become a part of the medical record. In the event that a midwife is attending the birth of a child, the protocol agreed upon by the physician and midwife shall ensure compliance with this rule.

641—4.3(136A) Time sequence for screening tests. The specimen (blood) shall be drawn from the infant at least 24 hours after birth, but not later than five days after birth. In any event, screening should be done prior to discharge. A second test shall be performed by 14 days of age when:

1. The first test was done prior to 24 hours after birth.
2. The first test was done while the infant was on antibiotic therapy. The second test shall be done at least 24 hours after the infant is off antibiotic therapy.

All specimens shall be forwarded by first-class mail, or other appropriate means, to the central laboratory designated by the birth defects institute within 24 hours after collection.

641—4.4(136A) Unattended birth. When a birth occurs that is not attended by a health professional, the county registrar shall inform the parents or guardians, when a certificate of birth is filed, of the need for a newborn blood test for hereditary metabolic disorders. The registrar shall also inform parents or guardians where the specimen may be collected.

641—4.5(136A) Central laboratory. Specimens shall be submitted to the central laboratory designated by the birth defects institute.

4.5(1) The central laboratory shall test specimens within 24 hours of receipt. The central laboratory shall notify the submitting physician or birthing facility of an inappropriate specimen and request an additional specimen.

4.5(2) Reports of presumptive positive results are made within 24 hours to the consulting physician, or the physician's designee, who then notifies the attending physician. This initial report is to be followed within 24 hours by a written report to the attending physician and birthing facility.

4.5(3) A consulting physician shall be designated by the birth defects institute in collaboration with the central laboratory to provide interpretation of test results and consultation to attending physicians.

4.5(4) The central laboratory shall submit a semiannual report to the birth defects institute. These reports shall include:

a. Monthly activity report.
(1) Number of infants tested by birthing facility.
(2) Number of repeat tests by birthing facility.
(3) Number of presumptive positive results by test and facility.
(4) Number of confirmed positive results by test.
(5) Results of quality assurance testing.
b. Annual report detailing screening activity, fiscal accounting and educational activity.

4.5(5) The central laboratory shall distribute specimen collection forms and other materials to birthing facilities as required.

4.5(6) The central laboratory shall provide educational materials concerning specimen collection procedures.

4.5(7) The central laboratory shall have available for review a written quality assurance program covering all aspects of its newborn screening activity.

4.5(8) The central laboratory shall act as fiscal agent for program charges. The charges will encompass analytical, technical, administrative, educational, and follow-up for the screening program.

4.5(9) Sixty days prior to the end of the fiscal year all activities associated with this program (central laboratory, consulting physician, and fiscal agent) shall submit a combined program proposal and budget to the Iowa department of public health for the birth defects institute for the coming year.

The Iowa department of public health shall annually review and determine the fee to be charged for all activities associated with this program. The review and fee determination will be completed at least one month prior to the beginning of the fiscal year.

641—4.6(136A) Expanded MSAFP testing policy. Expanded Maternal Serum Alpha-Fetoprotein (MSAFP) screening will be available. If patients desire this screening test and specimens are drawn, specimens shall be submitted by their physicians to the central laboratory. A serum or clotted blood specimen shall be collected during 15 to 20 weeks of pregnancy, accompanied by a standard test request form, all contained in a specimen kit provided by the central screening laboratory.

4.6(1) The central laboratory shall test specimens within three working days of receipt. Abnormal expanded MSAFP test results are reported within 24 hours to the consulting physician or the physician's designee who then notifies the submitting physician. On the next working day this initial report is to be followed by a written report to the submitting physician.

4.6(2) A consulting physician shall be designated by the birth defects institute in collaboration with the central laboratory to provide interpretation of test results and consultation to attending physicians.

4.6(3) The consulting physician will develop and provide professional educational presentations as necessary.

4.6(4) The central laboratory shall submit a monthly report detailing screening activity to the consulting physician. This report shall include:

a. Number of initial tests.

b. Number of repeat tests.

c. Number of confirmed abnormal results.

d. Results of quality assurance testing.

4.6(5) The consulting physician shall submit a required report to the birth defects institute. These reports shall include:

a. Number and type of outcomes of presumptive abnormal expanded MSAFP tests.

b. Consultative activity.

c. Educational activity.

d. Fiscal report identifying expenditures.

4.6(6) The central laboratory shall distribute specimen collection forms and other materials to birthing facilities as required.

4.6(7) The central laboratory shall provide educational materials concerning specimen collection procedures.

4.6(8) The central laboratory shall have available for review a written quality assurance program covering all aspects of its testing activity.

4.6(9) The central laboratory shall act as a fiscal agent for program charges. The charges will encompass analytical, technical, administrative, educational and follow-up costs for the screening program.

4.6(10) Sixty days prior to the end of the fiscal year, all activities associated with this program (central laboratory, consulting physician and fiscal agent) shall submit a combined program proposal and budget to the Iowa department of public health for the birth defects institute for the coming year.

The Iowa department of public health shall annually review and determine the fee to be charged for activities associated with this program. The review and fee determination will be completed at least one month prior to the beginning of the fiscal year.

641—4.7(136A) Regional genetic consultation service (RGCS). Comprehensive genetic services are available statewide through outreach clinics.

4.7(1) *Regional genetic consultation service patient fees.* A sliding fee scale shall be established for patients attending genetic counseling clinics. Fees charged at RGCS clinics are based upon hourly wages of professional (medical geneticists, regional consultants), support and clerical staff, travel and supply costs associated with clinic service.

4.7(2) *Clinic service.* The service provided at the clinic may include:

a. Consultations by board-certified geneticists.

b. Physical examinations.

c. Information regarding the diagnosis, including inheritance patterns, prognosis, and risk for future pregnancies.

d. Medical management.

e. Referral to appropriate agencies.

4.7(3) *Billable services.* Families/clients seen in the regional genetic consultation service clinics will have bills submitted to third-party payers where applicable. Families/clients who do not have third-party coverage will be billed on a sliding fee scale. The sliding fee scale will be established using the federal government (Community Service Administration) poverty guidelines. The birth defects advisory committee will approve the sliding fee guidelines on an annual basis. Billing will be done by the Iowa department of public health staff or its designee. Payments received from receipts of service based on the sliding fee scale or from the third-party payers shall be used to support the RGCS.

These rules are intended to implement Iowa Code chapter 136A.

[Filed November 20, 1970]
[Filed 2/12/82, Notice 12/23/81—published 3/3/82, effective 4/7/82]
[Filed emergency 7/15/83—published 8/3/83, effective 7/15/83]
[Filed emergency 9/23/83—published 10/12/83, effective 9/23/83]
[Filed emergency 5/11/84—published 6/6/84, effective 5/11/84]
[Filed 11/15/85, Notice 8/14/85—published 12/4/85, effective 1/8/86]
[Filed 12/8/86, Notice 9/24/86—published 12/31/86, effective 2/4/87]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 11/30/87, Notice 10/21/87—published 12/16/87, effective 1/20/88]
[Filed 1/10/92, Notice 8/7/91—published 2/5/92, effective 3/11/92]
[Filed emergency 7/14/95 after Notice 6/7/95—published 8/2/95, effective 7/14/95]